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**Foreword**

We present a summary of the internal research activity at the Royal Hospital for Women for 2013.

As can be seen, the Royal is a highly active research institution, in all areas of Perinatal care. A large number of staff, from midwifery, obstetrics, neonatal nursing and neonatology have contributed to this research activity. In particular we are grateful to Dr. Maryam Sana who has been responsible for collating this information over the last months, and for maintaining a database of all current internal trials. We are grateful to the Royal Hospital for Women Foundation for their support for Maryam’s role and for their recognition of the importance of coordination of research output.

The Perinatal Academic Group (PAG) has been successfully reviewing all research activities at the RHW in 2013, discussing resource implications and overseeing a research strategy for the future. PAG meetings act to ensure that conflict between research studies is minimised by having oversight of all current internal and external research. The PAG Terms of Reference (TOR) can be found on RHW “P” drive in the folder labelled as “Perinatal Research Activity”.

The Wednesday Academic Lunch Time Meetings have also been running successfully in 2013, for which we again thank the Foundation for support. These meetings aim to provide a forum for multidisciplinary discussion of evidence based clinical practice, dissemination of new information, presentation of research findings and discussion of current hot topics and controversies.

We would also like to acknowledge the Royal Hospital for Women Foundation for their generous support for the Midwifery Research Fellow, Dr Donna Hartz, who was enabled to continue her research during 2013 based at the Midwifery and Women’s Health Research Unit Royal Hospital for Women and the University of Sydney.

Our sincere thanks go to the Royal Hospital for Women Foundation who continue to generously support the research capacity of the Royal.

We have endeavoured to contact all research active members of the perinatal research group and if for a reason you missed that, we will encourage you to present in the next year’s research activity document. We thank all those involved for their input to this document and look forward to further ongoing research collaboration and further improvement in the output from RHW.

Sally K Tracy

Professor Alec Welsh
Professor in Maternal-Fetal Medicine
University of New South Wales
Royal Hospital for Women

Professor Sally Tracy
Professor of Midwifery
University of Sydney
Royal Hospital for Women
Outstanding Achievement in 2013

The Lancet Press Release 17th September 2013

One-to-one Midwife Care just as Safe and Costs Significantly Less than Current Maternity Care

Continued care from a named midwife throughout pregnancy, birth, and after the baby is born (caseload midwifery) is just as safe as standard maternity care (shared between rostered midwives, and medical practitioners in discrete wards or clinics) for all women irrespective of risk, and is significantly cheaper, according to new research published in The Lancet.

"Caseload midwifery costs roughly AUS$566.00 (£333.00) less per woman than current maternity care, with similar outcomes for women of any risk, and could play a major part in reducing public health expenditure in countries like the UK and Australia where standard maternity care is shared between different health professionals”, explains study leader Professor Sally Tracy from the University of Sydney in Australia.

The Midwives @ New Group practice Options (M@NGO) study randomly assigned pregnant women (aged 18 or older) from two metropolitan teaching hospitals in Australia to a named caseload midwife (or back-up caseload midwife; 871 women) or standard shared care with rostered midwives and medical practitioners (877), to compare outcomes for mothers and babies and cost of care.

The researchers noted no difference between the groups in number of caesareans, use of epidurals, instrumental births, 5-minute Apgar scores of 7 or less (a system for determining a newborn's health using a scale of 0 to 10, with 10 being the healthiest), admission to neonatal intensive care, or preterm birth.

However, women who received caseload midwifery care were less likely to have an elective caesarean (before the onset of labour), more likely to have a spontaneous labour, required less pain drugs and had less blood loss following birth, needed to stay in hospital for less time, and had improved breastfeeding rates—which together, say the authors, accounted for the lower cost of caseload midwifery.

According to Tracy, “The caseload model of midwifery has been largely overlooked in maternity systems because of a perception that the service will be too expensive and that the model is not safe for complex pregnancies. Our results show that in women of any risk caseload midwifery is safe and cost effective.”

Commenting on the study, Petra ten Hoope-Bender from Instituto de Cooperación Social Integrare in Switzerland says, “A health system that makes caseload midwifery services available to all women would provide the right services to the right women at the right time. Such an approach can reduce unnecessary interventions, iatrogenic harm, deaths, and costs. It can also strengthen the health and wellbeing of women, the start of the early years of life, and the capabilities of women to take care of their families and themselves..A crucial final piece in this study is the analysis of women’s satisfaction with caseload midwifery, to which I would recommend investigators add the satisfaction and workload of midwives.”

Professor Sally Tracy, University of Sydney, New South Wales, Australia. T) +61420277106 E) sally.tracy@sydney.edu.au

Dr Petra ten Hoope-Bender, Instituto de Cooperación Social Integrare, Geneva, Switzerland. E) petra.tenhoope@integrare.es
Peer-Reviewed Publications 2013
Peer-Reviewed Publications 2013


Abstracts and Presentations 2013


27. NSW Women’s Health Nurses annual conference in November: An update on Midwifery Models of Care.


43. Austin, M. P. Screening for post-natal depression: The universal Perinatal Psychosocial Screening Program. Presented at the Disease Screening: Sensitivities and specifics, Milsons Point, Sydney (3rd May 2013).

Internally-based Obstetric, Midwifery & Neonatology Projects
List of Internal Obstetrics, Midwifery and Neonatology Research Projects-RHW 2013

A. Recruitment Started in 2013 and Continues in 2014:

1. Is Lactic Acid Concentration in Amniotic Fluid a New Predictor of Labour Dystocia? The Amniotic Fluid Lactate Study - NHMRC funded
   The Amniotic Fluid Lactate study aims to determine whether a point of care test (the lactate test) is a useful tool for clinicians to assist in the diagnosis of failure to progress in labour (labour dystocia).
   For details please contact
   Sally Tracy  sally.tracy@sydney.edu.au; sally.tracy@sesiachs.health.nsw.gov.au
   Beverly Hall  Beverley.Hall@sesiachs.health.nsw.gov.au

2. ENDIA study - NHMRC funded
   Early Environmental Determinants of Pancreatic Islet Autoimmunity: a Pregnancy to Early Life Cohort Study in Children at Risk of Type 1 Diabetes - (T1D)
   The aim of this study is to follow 1400 children who have a first-degree relative with T1D, initially during pregnancy and the first 3 years of life, to determine how genotype and changes in weight, insulin sensitivity, metabolome, lipidome, microbiome, vitamin D, omega 3 fatty acid and nutritional status, and the timing and frequency of viral infections, relate to the development of islet autoimmunity.
   For further details please contact
   Prof Jennifer Couper
   Endocrinology and Diabetes
   Women’s and Children’s Hospital
   North Adelaide
   SA 5006.

   Jackie Catteau
   Jackie.Catteau@sesiachs.health.nsw.gov.au

3. APTS – Australian Placental Transfusion - NHMRC funded
   The APTS is a randomised controlled trial and aims to establish if delayed cord clamping in preterm babies less than 30 weeks gestation will improve health outcomes compared with the standard practice of early cord clamping.
   For details please contact:
   Kei Lui
   Director of Newborn Care Centre
   Royal Hospital for Women
   Email: kei.lui@sesiachs.health.nsw.gov.au
4. Impact on Caesarean Section Rates Following Injections of Sterile Water (ICARIS) - NHMRC funded
The aim of this study is to determine if sterile water injections into the lower back to relieve back pain in labour, may also reduce the caesarean section (CS) rate.
For further details please contact:
Dr. Donna Hartz Donna.Hartz@sydney.edu.au

5. NSW Antenatal and Aboriginal Screening Investigation Study (NAANSI Study) - NHMRC funded
The NAANSI study is being undertaken by a research team from the University of New South Wales on Aboriginal and non Aboriginal women’s experience of antenatal assessment. One of the key focuses of the research will be the domestic violence screening questions. Previous research by the Chief Investigator, Jo Spangaro and other members of the team developed a preliminary model explaining how women made decisions to disclose abuse when asked the screening questions as well as their perceptions about its impact.
For details please contact
Joanne Spangaro j.spangaro@unsw.edu.au

6. The Lactoferrin Infant Feeding Trial (LIFT)
The LIFT study is a pragmatic, randomized clinical trial in 1,500 very low birth weight infants (VLBW: <1,500 g) to test the hypothesis that adding bovine lactoferrin (bLF) vs placebo to feeds improves the primary composite outcome of all-cause hospital mortality or any of 5 morbidities diagnosed or treated in hospital.
For details please contact:
Kei Lui
Director of Newborn Care Centre
Royal Hospital for Women
Email: kei.lui@sesiahs.health.nsw.gov.au

7. Fetal Oxygenation Myocardial Performance Index Sub-study (FOX MPI Sub-study)
This is a sub-study of FOX (Fetal Oxygenation Study). FOX MPI will investigate the role of functional fetal cardiac imaging (MPI and AoI) and cCTG in predicting fetal compromise in IUGR babies and determine the relative utility of these measures as stand-alone tests and when used concurrently to best inform about the timing of birth.
For further details please contact:
Organising centre, FOX study:
Mercy Hospital for Women, 163 Studley Rd., Heidelberg 3084, Vic
Dr Clare Whitehead clarew@unimelb.edu.au
Associate Professor Stephen Tong stong@unimelb.edu.au
Professor Susan Walker spwalker@unimelb.edu.au
Study investigators, FOX MPI sub-study
Royal Hospital for Women, Barker St, Randwick NSW 2031
Dr Amanda Henry
Amanda.Henry@unsw.edu.au
Professor Alec Welsh
Alec.Welsh@unsw.edu.au
Ms Jennifer Sanderson
Jennifer.Sanderson@unsw.edu.au

8. Magnesium Sulphate at 30 to 34 weeks’ Gestational Age: Neuroprotection Trial
The aim of this randomised controlled trial is to assess whether giving Magnesium Sulphate compared with placebo to women immediately prior to the preterm birth between 30 and 34 weeks’ gestation reduces the risk of death or cerebral palsy in their children at 2 years’ corrected age.
For details please contact:
Professor Caroline Crowther
ARCH: Australian Research Centre for Health of Women and Babies
Caroline.crowther@adelaide.edu.au

9. The PreP 21 Study
PREDICTING AND PREVENTING LEUKAEMIA IN CHILDREN WITH DOWN SYNDROME
The aim of this study is to establish a population based GATA-1 mutation screening test that may predict progression from transient myeloproliferative disorder (TMD) to Acute Megakaryoblastic leukemia (AMKL) in children with Down syndrome. In addition, it will also evaluate the true incidence of subclinical TMD and explore its relationship to the subsequent formation of AMKL.
For further details please contact:
Glenn Marshall, Kids Cancer Centre, Level 1 South, Sydney Children’s Hospital,
Email: g.marshall@unsw.edu.au
Dr Marion Mateos, Kids Cancer Centre, Level 1 South, Sydney Children’s Hospital,
Email: m.mateos@unsw.edu.au
Study Co-ordinator Ms Sally Byatt, Kids Cancer Centre, Level 1 South, Sydney Children’s Hospital,
Email: sallyanne.byatt@sesiahs.health.nsw.gov.au
10. POP OUT Trial
Persistent Occipto-Posterior Position: Outcomes following manual rotation.
The primary hypothesis for this study is that performing a manual rotation at full dilatation at term for either OP or OT position will result in a reduction of operative delivery.
For further details please contact
A/P Andrew Bisits
Royal Hospital for Women
Andrew.bisits@sesiahs.health.nsw.gov.au

11. The Sweet Study
The Glycaemia Effect of Betamethasone in Women with Diabetes in Pregnancy
This is an observational study which will allow development of a management protocol for control of maternal blood sugars in women with diabetes in pregnancy requiring betamethasone.
For further details please contact
Dr. Sandra Lowe
Sandra.lowe@sesiahs.health.nsw.gov.au

12. Venous Thromboemolus (VTE) Prophylaxis following Post Partum Haemorrhage (PPH): Retrospective review of current practice and complications following thromboprophylaxis in women who experience massive postpartum haemorrhage.

Short Title:
Correlation of VTE and PPH
It is a retrospective audit of data including women who have experienced a massive PPH (>1000, >1500ml), deep venous thrombosis (DVT), pulmonary embolus (PE) between January 2008 and January 2012.
For further details please contact
A/Prof, Dr Andrew Bisits
Epidemiology, Master of Medical Statistics
Royal Hospital for Women
Andrew.bisits@sesiahs.health.nsw.gov.au
Dr Svetlana Starodubtseva
SRMO, Royal Hospital for Women
Svetlana.starodubtseva@sesihs.health.nsw.gov.au
13. Intravenous Iron Use in Pregnant Patients: an observational study of maternal and fetal outcomes
This study consists of a retrospective audit of all pregnant women who received intravenous iron sucrose (from January 1st, 2007 till 31st December 2010) or intravenous FCM (from 1st June 2012 till 31st July 2013) at the Royal Hospital for Women.
For further details please contact:
Principal Investigator: Ms Selina Boughton
Email: Selina.boughton@sesiahs.health.nsw.gov.au
Co Investigator: Dr Amanda Henry
Email: Amanda.henry@unsw.edu.au
Co Investigator: Dr Giselle Kidson-Gerber
Email: Giselle.kidson-gerber@sesiahs.health.nsw.gov.au

14. The Use of Bimanual Examination for Clot Evacuation in the Management of Postpartum Haemorrhage
This study is a retrospective audit of the management of PPH at the Royal Hospital for Women. The aims are to audit the use of bimanual examination for clot evacuation in the management of postpartum haemorrhage and its timing, and to correlate this to the need for further surgical management. The hypothesis to be tested is whether early use of bimanual clot evacuation in the management of PPH reduces the need for subsequent operative management.
For further details please contact:
Dr. Pui Ru Koh
Registrar
Associate Professor Andrew Bisits
Director of Obstetrics/ Maternity Services, Obstetrics
Royal Hospital for Women
andrew.bisits@sesiahs.health.nsw.gov.au

15. The N3RO Trial
Docosahexaenoic Acid for the Reduction of Bronchopulmonary Dysplasia in Preterm Infants Born at Less than 29 weeks Gestational Age: a Randomised Controlled Trial.
The aim of this study is to determine the degree to which Docosahexaenoic acid (DHA) supplementation reduces the incidence of bronchopulmonary dysplasia (BPD), as assessed by the requirement for supplemental oxygen and/or assisted ventilation at 36 weeks post menstrual age.
For further details:
Dr Carmel Collins
Women’s and Children’s Health Research Institute
Email: carmel.collins@health.sa.gov.au

Dr. Srinivas Bolisetty
Royal Hospital for Women
Email: srinivas.bolisetty@sesiahs.health.nsw.gov.au
B. Recruitment Ongoing in 2014:

1. Targeted Oxygenation in The Development of Premature Infants and Their Developmental Outcome – the TO$_2$RPIDO Study (NHMRC funded)
   The TO$_2$RPIDO study aims to determine the outcomes of premature infants below 32 weeks gestation who are resuscitated with either 100% oxygen (100% O$_2$) or 21% oxygen (room air, RA) that is titrated to achieve specific pre-ductal SpO$_2$ levels. For details please contact:
   Julee Oei
   Newborn Care Centre
   Royal Hospital for Women
   Email: julee.oei@sesiahs.health.nsw.gov.au

C. Recruitment Starts in 2014:

1. The Capacity for informed Consent during Labour
   **Short title:** “Capacity for informed consent during labour”.
   This pilot study aims to determine the capacity of pregnant women to comprehend and retain information (pregnancy and non-pregnancy related) during labour. For further details please contact
   Ms Laura Pierson  
   I.pierson@yahoo.com
   Prof Alec Welsh  
   Alec.Welsh@unsw.edu.au
   Dr. Amanda Henry  
   Amanda.henry@unsw.edu.au

   This cross-sectional survey aims to determine the overall use of herbal and dietary supplements and specifically iron supplements before and during pregnancy. For further details please contact:
   Dr.Antonia Shand
   Antonia.Shand@sesiahs.health.nsw.gov.au

3. Parental Response to Fetal or Postnatal Diagnosis of Congenital Heart Disease and Subsequent Infant Development Outcomes (CHERISH).
   This prospective cohort study will examine the prevalence and correlates of psychological morbidity in parents following fetal or postnatal diagnosis of major CHD in their infant. Of key concern, is the association between maternal stress and anxiety during pregnancy, and later infant emotional, behavioural, and neurodevelopmental outcomes. For details please contact:
   Website: www.heartcentreforchildren.com.au
   Dr Nadine Angele Kasparian  
   n.kasparian@unsw.edu.au
   Dianne Swinsburg  
   d.swinsburg@unsw.edu.au
4. When Does the Neonate Start Forming Rouleaux? (Neonatal Rouleaux Study)
The aim of this study is to qualitatively assess rouleaux formation by blood film examination at the time of birth and during the first two weeks of life.

For further details please contact:
Dr Timothy Schindler
Tim.Schindler@sesiahs.health.nsw.gov.au

5. A Family Integrated Care Model for NICU.
Short Title:
FiCare
This study will evaluate the efficacy of the Family Integrated Care model in a multi-center cluster randomized controlled trial of 16 NICUs across Canada and Australia.
For further details please contact:
A/P Kei Lui
Kei.lui@sesiahs.health.nsw.gov.au
D. Honours Projects:

1. Recruitment Starts in 2014:

1. Correlation and Synergy between the Delta Myocardial Performance Index (MPI) and Aortic Isthmus Index as Markers of Unilateral Fetal Cardiac Strain. (Aortic Isthmus Study)
This honours project aims to determine the correlation between the Aortic Isthmus Index and the Delta MPI as both have been proposed as useful markers for unilateral fetal cardiac function or strain.
For further details please contact:
Dominique Tynan dom.tynan@gmail.com
Dr. Amanda Henry Amanda.henry@unsw.edu.au
Prof. Alec Welsh alec.welsh@unsw.edu.au

2. Application of Automation to the Fetal Myocardial Performance Index (MPI) to Determine Repeatability of a Digital System Compared with Human Measurement
The main hypothesis of this study is that an automated technique for measurement of the fetal MPI will be more repeatable than currently used subjective methodology.
For further details please contact:
Priya Maheshwari priya1maheshwari@yahoo.com.au
Dr. Amanda Henry Amanda.henry@unsw.edu.au
Prof. Alec Welsh alec.welsh@unsw.edu.au

E. Independent Learning Projects (ILP):

1. Recruitment Finished in 2013:

1. Outcomes of Stage 1 Twin-Twin Transfusion Syndrome (TTTS) Referred to the NSW Fetal therapy Centre: the NSW Perspective
This study aimed to evaluate the outcome for cases referred to the NSW Fetal Therapy Centre as Stage 1 TTTS; to gain an understanding of current therapeutic strategies for TTTS including the potential for providing laser therapy for stage 1 TTTS; and to compare progression and regression of TTTS in our local population with the international literature.
For details please contact:
Ms Elen Hinch z3375990@student.unsw.edu.au
Alec Welsh alec.welsh@unsw.edu.au
Amanda Henry amanda.henry@unsw.edu.au
2. Twin Laser Outcome Study
An Audit of Immediate Outcomes for Monochorionic Diamniotic Twins Following Laser Therapy for Twin-Twin Transfusion Syndrome.

This project aimed to update the previous audit of the outcomes of the monochorionic twins undergoing laser therapy at the RHW. Laser therapy for twin-twin transfusion syndrome has been performed at the RHW since June 2003. A previous audit of the cases between June 2003 to June 2008 was published in 2010. The study investigators tried to update this by focusing upon immediate survival of twins in the neonatal period. For details please contact:
Ms Isabella Wilson  z3376844@student.unsw.edu.au
Alec Welsh  alec.welsh@unsw.edu.au
Amanda Henry  amanda.henry@unsw.edu.au

2. Recruitment Starts in 2014:

1. Breastfeeding and the Developmental Outcomes of Very Premature Infants-ILP Project
The aim of this study is to compare the neurodevelopmental outcomes at corrected age 2-3 years between breast fed and formula fed infants at discharge born at GA <29 completed weeks using a population based retrospective cohort study of infants treated in 10 NICUs in NSW & the ACT between January 1 2001 and December 31 2009. For further details please contact:
A/P Kei Lui
Kei.lui@sesiahs.health.nsw.gov.au

2. TAPS and TRAPS
Uncommon Complications of Monochromic Twin Pregnancies: Twin Anemia Polycythemia Syndrome (TAPS) and Twin Reversed Arterial Perfusion (TRAP)
The aim of this study is to conduct an audit of pregnancy management and immediate outcomes of monochromic diamniotic twin pregnancies affected by TAP or TRAP sequence. For further details please contact:
Ms Katie Fischer  Katie_fischer_6@gmail.com
Dr. Amanda Henry  Amanda.henry@unsw.edu.au
Prof. Alec Welsh  alec.welsh@unsw.edu.au
3. The Role of Myocardial Performance Index in Complicated Monochorionic Twin Pregnancies

This study aims to compare ventricular function in complicated monochorionic, diamniotic (MCDA) twin pregnancies versus uncomplicated MCDA pregnancies, through use of the ultrasound-derived Myocardial Performance Index (MPI).

For further details please contact:
Ms Saranya Gopikrishna  saranya.gopikrishna@gmail.com
Dr. Amanda Henry  Amanda.henry@unsw.edu.au
Prof. Alec Welsh  alec.welsh@unsw.edu.au

4. Diabetes Mellitus in Mothers with Twin Pregnancy

This is a retrospective cohort study of women with a twin pregnancy who booked and delivered between January 2004 and December 2013, at Royal Hospital for Women (RHW), Randwick.

For further details please contact:
Dr. Antonia Shand  Antonia.Shand@sesiahs.health.nsw.gov.au
Research Project Summaries
Details of Internal Obstetrics, Midwifery and Neonatology Research Projects RHW-2012

A. Recruitment Started in 2013 and Continues in 2014:

1. Is Lactic Acid Concentration in Amniotic Fluid a New Predictor of Labour Dystocia? The Amniotic Fluid Lactate Study

**NHMRC Funded**

The Amniotic Fluid Lactate study is a prospective cohort study designed to determine the correlation between higher concentrations of amniotic fluid lactate and the diagnosis of labour dystocia. The research involves testing small samples of amniotic fluid with a hand held lactate meter to measure the concentration of lactate at predefined time intervals during the labour process when amniotic fluid is naturally expelled. Labour dystocia is a serious problem experienced during childbirth, and is one of the main indications for caesarean section. Although it is a common clinical problem worldwide, the definition is highly imprecise as is the timing of necessary intervention. In practice a large variation exists in the recognition of dystocia increasing the risk that the timing or necessity to intervene may be inaccurate. A study sample of 1940 nulliparous women is required to determine the precision of amniotic lactate as a diagnostic test utilising a binomial distribution, significance level of $p = 0.05$, sensitivity of 0.85, and lower limit of sensitivity 0.80 and 30% attrition rate. Analyses will follow the Standards for Reporting of Diagnostic Accuracy (STARD) with 95% confidence intervals. This research has the potential to offer a new level of precision in assessing labour dystocia and be internationally significant, placing Australia at the forefront of applying recent advances in physiological research into clinical practice in maternity services.

**Contact Details:**

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Randwick NSW 2031  
Australia  
sally.tracy@sydney.edu.au

Beverly Hall  
Midwifery and Women's Health Nursing Research Unit  
Royal Hospital for Women  
Beverley.Hall@sesiahs.health.nsw.gov.au
2. ENDIA study - NHMRC funded

Early Environmental Determinants of Pancreatic Islet Autoimmunity: a Pregnancy to Early Life Cohort Study in Children at Risk of Type 1 Diabetes - (T1D)

Study Design:
Prospective study from pregnancy into the first 3 years of life, as the first stage of an ongoing cohort study

Study Population:
- Pregnant women and their unborn children where the latter have a first-degree relative with T1D.
- Infants aged up to 6 months, who have a first-degree relative with T1D.

Objectives:
- To follow 1400 children who have a first-degree relative with T1D, initially during pregnancy and the first 3 years of life, to determine how genotype and changes in weight, insulin sensitivity, metabolome, lipidome, microbiome, vitamin D, omega 3 fatty acid and nutritional status, and the timing and frequency of viral infections, relate to the development of islet autoimmunity.
- To follow these children longer-term into adolescence to determine the relationship between genotype and early environment and the development of islet autoimmunity and T1D.

Primary Outcome Measure:
Development of islet autoimmunity defined as persistent elevation of > 1 islet autoantibody on consecutive 6 monthly tests (excludes transient, low titre autoantibodies).

Secondary Outcome Measure:
Development of T1D

Study Design:
1400 pregnant women with T1D, or where the unborn child has a first-degree relative with T1D, will be recruited during the pregnancy and their children followed during the first 3 years of life to determine genotype and changes in weight, insulin sensitivity, metabolome, lipidome and microbiome, vitamin D, omega 3 fatty acid and nutritional status, and the timing and frequency of viral infection; and to determine the relationship between these environmental variables and the development of islet autoimmunity. Investigation will be during pregnancy (1 – 3 points in the first, second, and third trimesters depending on the time of recruitment) and 3 monthly after birth for 2 years, then 6 monthly. The primary outcome measure is persistent islet autoimmunity, with a 90% power to detect a 7% difference in risk of islet autoimmunity. Parametric and non-parametric survival models will calculate the effect of variables on the risk of islet autoimmunity.

Recruitment and Withdrawal of Subjects:

Inclusion Criteria:
- Unborn child with first degree relative with T1D (Mother in first, second or third trimester of pregnancy).
- While every effort will be made to recruit and begin investigation as early as possible during the pregnancy, mothers eligible for the study who have given birth will be able to enrol their infant into the study up until 6 months of age.

Exclusion Criteria:
None

Number of Participants
1400

Study Duration
2013-2016
3. APTS – Australian Placental Transfusion (NHMRC funded)
A randomised controlled trial

Primary Clinical Hypothesis:
Should very preterm babies receive a placental transfusion at birth?
An autologous transfusion of placental blood at birth will improve health outcomes in preterm babies. Placental transfusion by deferred cord clamping is associated with an 8% absolute risk difference, from 30% to 22% in mortality and/or major morbidity, at 36 weeks post menstrual age.

Study Objective:
To establish if placental transfusion in preterm babies less than 30 weeks gestation will improve health outcomes compared with the standard practice of early cord clamping.

Study Design:
This is a multicentre 2-arm parallel open label randomised controlled trial.

Participant Population:
Male or female pre term babies less than 30 weeks gestational age.

Inclusion Criteria:
- Mother imminently delivering < 30 weeks of gestation
- Informed consent has been received from a parent

Exclusion Criteria:
No indication or contraindication to placental transfusion, in view of parent or doctor. For example, contraindications may include
- Fetal haemolytic disease
- Fetal hydrops
- Major malformations considered incompatible with survival

Withdrawal Criteria:
Any family that wishes to withdraw from the trial may do so, without giving a reason and without any change in any other aspect of treatment. Parents of any baby who is withdrawn from the study after randomisation and before or after the intervention is administered will be asked to allow collection of outcome data. Information on hospital outcomes for any baby who is withdrawn after the baby is discharged from hospital will be used in the study.

Study Interventions:
The two arms of the trial comprise:
(a) early cord clamping (which is the control arm)
(b) deferred cord clamping (for 60 seconds or more with the baby held below or at the level of the placenta)

Study Population: babies of 29 weeks gestation or less

Primary Outcome:
Death and/or major morbidity at 36 weeks post menstrual age
Secondary Outcomes:
1. Death by 36 weeks postmenstrual age
2. Major morbidity at 36 weeks post menstrual age
3. Death and major morbidity in infants of 27\(^0\) weeks gestation or more
4. Death and major morbidity in infants of 26\(^6\) weeks gestation or less
5. Death or severe disability to (i) 24 months and (ii) 3 years corrected age

Tertiary (hypothesis generating) Outcomes Include:
Birth weight, number of exchange transfusions, number of partial exchange transfusions

Start Date of Recruitment:
Dec 2013.

End Date of Recruitment:
April 2016 with a further 24 months for follow-up i.e. total study duration of 72 months.

Contact Details:
Kei Lui
Director of Newborn Care Centre
Royal Hospital for Women
Email: kei.lui@sesiahs.health.nsw.gov.au

4. Impact on Caesarean Section Rates Following Injections of Sterile Water (ICARIS) - NHMRC funded

Aims
Primary aim: To determine if sterile water injections, as an intervention for back pain in labour, will reduce the in labour CS rate.
Secondary aims: To determine the effects of SWI for back pain in labour on:
- effectiveness for relieving back pain
- requirement for pain relief methods other than the intervention
- mode of birth and complications associated with birth (prior to hospital discharge)
- other maternal and infant outcomes in the immediate (six weeks) postnatal period
- cost of care for women and their babies during labour and birth, and the inpatient postnatal period from the perspective of the health system.

Study design
A randomised, placebo controlled, double blind trial where participants receive either SWI or injections of a normal saline placebo. This trial will be conducted across maternity centres in Queensland. The study protocol is registered on the Australian New Zealand Clinical Trials Registry (No ACTRN12611000221954).

Participants
Women in labour with lower back pain who satisfy the inclusion and exclusion criteria will be recruited from five Queensland maternity centres. Other maternity units in Queensland and interstate have expressed interest in participating in the trial and may be considered with regard to trial fidelity and funding. Ethical approval will be sought for each site prior to the commencement of recruitment

Inclusion criteria
Women who:
- Have a term singleton pregnancy (between 37 and 42 weeks gestation)
- Have a fetus in a cephalic (head down) presentation
- Experience back pain assessed by visual analogue scale VAS as ≥ 7 when women request analgesia for back pain
- Are able to provide informed consent.
Exclusion criteria
Women will be excluded if they fulfil any of the following criteria
- Multiple pregnancy
- Malpresentation (breech, transverse, shoulder)
- Previous CS
- Infection or inflammation at the injection sites or complications that could cause bleeding at injection site eg. Thrombocytopenia.

Contact details:
Chief Investigator:
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Professor of Midwifery,  
Midwifery Research Unit  
Australian Catholic University and Mater Medical Research Institute.  
Mater Health Services Brisbane, Queensland Australia

Dr. Donna Hartz  
Research Fellow  
Midwifery and Women's Health Research Unit  
The Royal Hospital for Women  
Organisation Name: The University of Sydney  
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5. NSW Antenatal and Aboriginal Screening Investigation (NAANSI Study- NHMRC funded)
The NAAnSI study is being undertaken by a research team from the University of New South Wales on Aboriginal and non Aboriginal women's experience of antenatal assessment. Assessing women for a range of risks as part of antenatal booking in has been introduced in NSW Health services in the last ten years to improve early intervention. It is important to understand what women think about being asked these questions including, how they decide whether and how much information to share.
One of the key focuses of the research will be the domestic violence screening questions. Previous research by the Chief Investigator, Jo Spangaro and other members of the team developed a preliminary model explaining how women made decisions to disclose abuse when asked the screening questions as well as their perceptions about its impact.

Sites: Royal Hospital for Women (Randwick), Blacktown and Nepean Antenatal clinics, Bulbul Werowe service at Mt Druitt Hospital, Malabar, Port Macquarie, Coffs Harbour, Macksville AMIHS and AMIHSes.

Inclusion Criteria:
The sample target is 120 pregnant women who have experienced abuse or fear of partner in the past 12 months.

Methodology:
The research team will directly approach women in the antenatal clinic waiting areas. Women who agree will be explained about the screening policy and will be offered a 20 minutes interview on the same day/subsequent appointment.

Recruitment and Interview: Data collection has just commenced at RHW following ethical approval by the Aboriginal Health and Medical Research Council HREC and the SESLHD HREC as lead ethics committee as well as Site Specific Assessment sign off by each LHD.

Starting Date:
Data collection will be done from Feb 2013 to June 2014.
Aim to have the Recruitment rate of approximately 3 women per week (40 women from Royal Hospital for Women).

**Recruitment End Date:**
May 2014

**Expected Date of Completion:**
March 2015.

**Contact Details:**
Dr. Joanne Spangaro
Research Fellow
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j.spangaro@unsw.edu.au

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6. Does Lactoferrin Reduce Mortality and Morbidity in Very Low Birth Weight Infants?

**The Lactoferrin Infant Feeding Trial (LIFT)**

**Aims and Hypothesis:**
The LIFT study is a pragmatic, randomized clinical trial in 1,500 very low birth weight infants (VLBW: <1,500 g) and aims to

- Test the hypotheses that adding bovine lactoferrin (bLF) vs placebo to feeds improves the primary composite outcome of all-cause hospital mortality or any of 5 morbidities diagnosed or treated in hospital: brain injury or chronic lung disease or retinopathy of prematurity (ROP) treated by local guidelines or late onset sepsis or necrotising enterocolitis (NEC); and secondary outcomes: (a) all-cause mortality after enrolment, (b) sepsis-related mortality, (c) brain injury, (d) chronic lung disease, (e) treated ROP, (f) late-onset sepsis, (f) NEC, (g) total volume of breastmilk given, (h) number of blood transfusions, (i) length of hospital stay; (j) growth to 36 weeks gestation; and
- To conduct a cost effectiveness analysis of bLF.

**Recruitment Start Date:**
November 2013

**Contact Details:**
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Royal Hospital for Women
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7. Fetal Oxygenation Myocardial Performance Index Substudy (FOX MPI sub-study)

At the Royal Hospital for Women, one of the intended recruitment sites for Fetal Oxygenation Study (FOX), we propose to perform a sub-study in which

- MPI and AoI are performed in addition to the other ultrasound measurements performed for FOX participants
- Computerised cardiotocograph (cCTG/Dawes-Redman criteria) is performed in preference to standard CTG
- Women in the IUGR (cases) group are offered the option of day of birth only ultrasound/CTG/maternal mRNA blood testing for study purposes, or serial study ultrasounds/CTG/maternal mRNA blood testing

**Inclusion Criteria:**
1) **Cases** – As for the FOX study, inclusion criteria for FOX-MPI are:
   - Severe fetal growth restriction (FGR)* requiring delivery <34 weeks gestation
   - Requires delivery because of non-reassuring or ambiguous tests of fetal wellbeing
- Delivery by Caesarean Section only
- No suspicions of infectious/structural/congenital/genetic abnormalities (i.e. the cause of FGR is thought to be placental in origin, not due to infection or underlying fetal anomaly)
- Written informed consent to participate
  * FGR defined by estimated fetal weight <10\text{th} centile and evidence of uteroplacental insufficiency - any/all of asymmetrical fetal growth, oligohydramnios, abnormal middle cerebral artery (MCA) Doppler, abnormal umbilical artery (UA) Doppler, abnormal ductus venosus (DV) Doppler flow.

2) **Controls** - As per the main FOX study protocol, inclusion criteria for controls are:
- Normal pregnancy, presenting at 28 weeks gestation
- Normal biometry, with estimated fetal weight 25\text{th}-75\text{th} centile and symmetrically grown
- Normal umbilical cord (UA) Doppler flows and normal middle cerebral artery (MCA) Dopplers
- Pregnancy ends as a term delivery of a well grown baby (>25\text{th} centile) NB This is a retrospective diagnosis and not known at the time of enrolment

**Sample Size**:
For the main FOX study, each site (including RHW) has been asked to recruit at least 20 day of delivery cases and 10 internal controls.
Total sample size for FOX-MPI will therefore be from 30-50 dependent on recruitment pattern. Total patients recruited will slightly exceed this number as not all controls recruited at 28 weeks will ultimately fulfil requirements for controls (term delivery, maternal blood collected at appropriate time points, cord gases obtained at delivery), and some cases may also not have sufficient essential data collected (e.g. maternal bloods not collected within 2 hours of delivery). Total enrollees will therefore be up to 60 patients to ensure adequate sample size and appropriate power for all groups.

**Contact Details:**
Organising centre, FOX study:
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Study investigators, FOX MPI sub-study
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Ms Jennifer Sanderson

8. **Magnesium Sulphate at 30 to 34 weeks’ Gestational Age:**
**Neuroprotection Trial (MAGENTA)**

**Aim:**
The aim of this randomised controlled trial is to assess whether giving Magnesium Sulphate compared with placebo to women immediately prior to the preterm birth between 30 and 34 weeks’ gestation reduces the risk of death or cerebral palsy in their children at 2 years’ corrected age.

**Study Design:**
Double-blind, multicentre, randomised, controlled trial.
Inclusion Criteria:
Women are eligible for the trial if they are at the risk of preterm birth between 30 and 34 weeks gestation where birth is planned or definitely expected within 24 hours, have a singleton or twin pregnancy, no contraindications to the use of antenatal magnesium sulphate (respiratory depression, hypotension, absent patellar reflexes, renal failure and myasthenia gravis) and give informed, written consent.

Exclusion Criteria:
Women are excluded if they have a higher order multiple pregnancy, have received magnesium sulphate in the same pregnancy or if magnesium sulphate therapy is considered essential for pre-eclampsia.

Trial Entry:
The eligible women are given the trial information sheet by the member of the research team and encouraged to discuss the study with family before the consent is sought.
The trial entry form is completed and the woman is randomised by contacting the central telephone randomisation service at the University of Adelaide. During the short telephone call, information is given to check the eligibility off the woman, describe the characteristics of woman and enable stratification at the randomisation centre, gestational age, number of fetuses. The randomisation schedule uses balanced variable blocks, and will be prepared by an investigator not involved with recruitment.
Assignment is to either the “magnesium sulphate group” or the “placebo group”. A unique study number and the trial treatment pack are allocated to the woman.
Royal Hospital for Women - antenatal ward and delivery suite.

Recruitment Start Date:
April 2013
End Date:
2016.

Contact Details:
Professor Caroline Crowther
ARCH: Australian Research Centre for Health of Women and Babies
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9. The PreP 21 Study
PREDICTING AND PREVENTING LEUKAEMIA IN CHILDREN WITH DOWN SYNDROME
Objectives:
1. To establish a population based GATA-1 mutation screening test that may predict progression from TMD to AMKL in children with Down syndrome.
2. To assess the level of GATA-1 gene mutations detected in children with Down syndrome found to have TMD/AMKL.
3. To identify factors which promote regression of TMD or subsequent progression to AMKL in children with Down syndrome?
4. To evaluate the true incidence of subclinical TMD and explore its relationship to the subsequent formation of AMKL.
5. To identify molecular targets that may be used as therapeutic targets for prevention of Down syndrome mediated leukaemogenesis.

Inclusion Criteria:
Participants may be enrolled on to the study once all eligibility requirements for the study have been met, including informed consent.
1. Age
Participants must be 2 years of age or younger, and ideally enrolled in the newborn period.

2. Diagnosis
Participants must have a cytogenetic confirmation of Down or mosaic Down syndrome.

3. Requirements for enrolment blood collection
An enrolment blood sample and full blood count is required within one month of birth, or at the time of enrolment for an older child.

**Exclusion Criteria:**
Participants that do not have consent for tumour banking are not eligible. Criteria for participants coming off protocol.
Participants will come off protocol once they develop any form of leukaemia or other malignancy. Parents/guardians must sign the consent form.
The study emphasis is to consent children with Down syndrome at birth; however children up to the age of 2 years are able to participate. Confirmation of Down syndrome and mosaic Down syndrome can be made by chromosome analysis.

**Contact details:**
For further details please contact:
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Study Co-ordinator Ms Sally Byatt, Kids Cancer Centre, Level 1 South, Sydney Children’s Hospital, Email: sallyanne.byatt@sesiahs.health.nsw.gov.au

10. POP OUT Trial
**Persistent Occipito-Posterior Position: Outcomes following manual rotation.**

**The primary hypothesis:**
The primary hypothesis for this study is that performing a manual rotation at full dilatation at term for either OP or OT position will result in a reduction of operative delivery.

**Study design:**
Double blind randomised controlled trial

**Inclusion criteria:**
Women eligible for randomization are those that are: At least 37 completed weeks of gestation; Planning a vaginal delivery; Have a cephalic presentation; Full cervical dilatation; Fetus in the OP or OT position confirmed by ultrasound. (OP position is defined as fetal occiput posterior with respect to the mother and within 45° of the midline[11].)

**Exclusion criteria:**
Most exclusion criteria were selected on the basis of predisposition to requiring an operative delivery such as the following: Clinical suspicion of cephalopelvic disproportion; previous caesarean section; brow or face presentation; “Pathologic” CTG according to RCOG classification plus either baseline >160 beats per minute or reduced variability for > 90 minutes; Fetal scalp pH < 7.25 or lactate > 4; Known major anatomical fetal abnormality (could influence safety or efficacy of manual rotation); Known or suspected chorioamnionitis; Intrapartum haemorrhage > 50mL; Temperature ≥38.0°C in the first stage of labour; Suspected fetal bleeding disorder (theoretical risks associated with procedures involving manipulation of fetal position); Pre-existing maternal diabetes.
Primary outcome:
Operative delivery (defined as caesarean section, forceps or ventouse delivery)
The links between operative delivery and associated short term and long term complications are well documented and provide a strong rationale for its choice as the primary outcome.

Secondary outcomes:
(1) Caesarean section
(2) Serious maternal morbidity or mortality (combined outcome):
This will include one or more of the following: Serious maternal morbidity defined as: post-partum haemorrhage requiring blood transfusion, third or fourth degree perineal trauma; dilatation and curettage for bleeding or retained placental tissue; cervical laceration; vertical uterine incision; vulvar or perineal haematoma requiring drainage; pneumonia; venous thromboembolism requiring anticoagulation; wound infection requiring prolonged hospital stay; readmission to hospital for obstetric related causes; wound dehiscence; maternal fever of at least 38.5°C on two occasions at least 24 hours apart, not including the first 24 hours; bladder, ureter or bowel injury requiring repair; genital-tract fistula; bowel obstruction; admission to intensive care unit; self reported depression requiring antidepressants
(3) Serious perinatal/neonatal morbidity, or mortality within 6 weeks of birth (combined outcome):

Contact details:
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Andrew.bisits@sesiahs.health.nsw.gov.au

11. The Sweet Study
The Glycaemia Effect of Betamethasone in Women with Diabetes in Pregnancy
Aims:
1. To quantify the impact of betamethasone administration on blood glucose levels in women with diabetes
2. To determine the optimal therapy for maintaining euglycemia in diabetic women given betamethasone
3. To quantitate the incidence of neonatal complications related to maternal diabetes ie hypoglycaemia and respiratory distress in the offspring of diabetic women given betamethasone

Method:
All women will be required to give written informed patient consent after review of the study information leaflet.
All women with diabetes prescribed betamethasone for fetal lung maturation will perform capillary blood glucose monitoring, at least qid [fasting and 1 or 2 hours postprandially] for 72 hours after the first injection of betamethasone, irrespective of whether or not they deliver. Following this period, there ongoing management will be as per usual practise.
A cohort (n=30) of gestationally matched women without diabetes will be enrolled from the antenatal ward, RHW. They will also have their capillary blood glucose tested as per the diabetic women ie qid for 72 hours after the first dose of betamethasone. These tests will be performed by nursing/midwifery staff at RHW.
This is an observational study and the information will be available to the regular caregivers.
Any change to their therapy will be recorded.
The neonates of diabetic women will have heel prick capillary blood glucose estimates as per current procedures for offspring of women with diabetes. The incidence of neonatal hypoglycaemia (<2.5 mmol/l), requirement for additional therapy for hypoglycaemia, admission to Newborn Care Centre or other complications will be recorded.

**Contact details:**
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Sandra.lowe@sesiahs.health.nsw.gov.au

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11. Venous Thromboemolus (VTE) prophylaxis following Post Partum Haemorrhage (PPH): Retrospective review of current practice and complications following thromboprophylaxis in women who experience massive postpartum haemorrhage.

**Short Title:**
Correlation of VTE and PPH

**Aims:**
The aims of this retrospective study are:
- To investigate the practice of VTE prophylaxis, specifically in women who have experienced a PPH at RHW by examining the data obtained from Obstetrix and including incidence of PPH, deep vein thrombosis, and pulmonary embolism. In addition, an overlapping extended 6 months-phased component of the study to identify potential thromboembolic complications that have arisen in this group of patients, examining the data from Medical records of Prince of Wales Hospital.
- To interpret the relationship between PPH and the risks of VTE, analyse the thromboprophylaxis protocol after a PPH and determine when it is appropriate to administer VTE prophylaxis after a patient has experienced a PPH.

**Methodology:**
Retrospective audit of data including women who have experienced a massive PPH (>1000, >1500ml), deep venous thrombosis (DVT), pulmonary embolus (PE) between January 2008 and January 2012.

The data will report results of recent thromboprophylaxis protocol after a massive PPH, the incidence of DVT and PE postpartum. Individual demographic data including ethnicity, maternal body mass index (BMI), parity, co-morbidities, mode of delivery and complications, length of labour, treatment PPH, DVT and PE. To determine time of thromboprophylaxis after the birth, what medications and for how long had been used (Clexane+/Heparin). Birth outcome, regarding gestational at birth, birth weight, Apgar score, interventions will be obtained from the Obstetrix database and electronic medical record (eMR) and patient notes. The association between PPH and the incidence of DVT, PE will be assessed from Obstetrix (RHW) and the medical record database (PWH).

**Place of recruitment:**
Royal Hospital for Women

**Time frame:**
01/06/2013 – 01/06/2014
Contact Details:
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12. Intravenous iron use in pregnant patients: an observational study of maternal and fetal outcomes

STUDY OBJECTIVES
Primary Objective
To compare the efficacy, feasibility and cost of using iron sucrose versus FCM to treat iron deficiency anaemia in pregnancy

Secondary objective
To compare the incidence of both maternal and fetal adverse events with intravenous iron sucrose or ferric carboxymaltose (FCM) in pregnant patients

STUDY Design

Design
This study consists of a retrospective audit of all pregnant women who received intravenous iron sucrose (from January 1st, 2007 till 31st December 2010) or intravenous FCM (from 1st June 2012 till 31st July 2013) at the Royal Hospital for Women.

Data collected will include baseline patient characteristics, obstetric/medical history, details and results of pathology tests, indication for iron infusion, follow-up that occurred post iron infusion and maternal/fetal outcomes on delivery (from review of existing Obstetrax database, NICUS, electronic medical records and patient medical notes).

Study Groups
1) Pregnant women receiving intravenous FCM from 1st June 2012-31st July 2013
2) Pregnant women receiving intravenous iron sucrose from 1st January, 2007-31st December 2010

Number of participants
Approximately 80 women who received either intravenous iron sucrose or FCM during the period of 1st January 2007 and 31st December 2010, and 1st June 2012 and 31st July 2013.

Number of centres
- One centre: Royal Hospital for Women, Randwick

Duration
- Estimate duration of study to take 10 months from 1st August 2013

Participant section

Inclusion Criteria
Pregnant females receiving intravenous FCM 1st June 2012-31st July 2013 or intravenous iron sucrose 1st Jan 2007-31st December 2010 (data previously collected and available in de-identified format)
Disease status: diagnosed iron-deficiency anaemia during pregnancy
Laboratory parameters: Hb, MCV, MCH, Ferritin

Exclusion Criteria
None identified
Contact Details:
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Co Investigator: Dr Amanda Henry
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Co Investigator: Dr Giselle Kidson-Gerber
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13. The Use of Bimanual Examination for Clot Evacuation in the Management of Postpartum Haemorrhage

Aims:
- To audit the use of bimanual examination for clot evacuation in the management of post-partum haemorrhage in women at the Royal Hospital for Women.
- The use of bimanual clot evacuation and the timing of this in addition to the various forms of medical management will be examined.
- The use of bimanual examination will be correlated to requirements for further surgical management in the operating theatre such as manual removal of placenta, balloon tamponade of the uterus, application of brace sutures, arterial ligation or hysterectomy.

This study is a retrospective audit of the management of PPH at the Royal Hospital for Women. Proposed hospital databases to be used for data collection include Obstetrix, Health information exchange (HIE), iPatient Manager (iPM), eMR, WRQ reflection (pathology results) and medical records. Cases will be vaginal deliveries, whether spontaneous or assisted.

Duration:
01/08/2013-01/08/2015

Contact Details:
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14. The N3RO Trial
Docosahexaenoic acid for the reduction of bronchopulmonary dysplasia in preterm infants born at less than 29 weeks gestational age: a randomised controlled trial.

Objectives:
To determine the degree to which Docosahexaenoic acid (DHA) supplementation reduces the incidence of bronchopulmonary dysplasia (BPD), as assessed by the requirement for supplemental oxygen and/or assisted ventilation at 36 weeks post menstrual age.

Design:
Randomised controlled trial

Outcomes:
Primary
BPD at 36 weeks post menstrual age.

Secondary
Any supplemental oxygen at 36 weeks post menstrual age, duration of respiratory support, length of hospital stay, growth rate, feeding tolerance, grade of intraventricular haemorrhage, confirmed sepsis, confirmed necrotising enterocolitis, grade of retinopathy of prematurity and death.

Study Duration:
The study will be conducted over a 3 year period 2013 to 2015 inclusive. Infants will receive treatment from enrolment until 36 weeks post menstrual age (PMA). Infants will be followed until 36 weeks PMA or to discharge home, whichever occurs first.

Interventions

Study Product:
1. Aqueous emulsion of DHA oil (tuna oil) containing 19.5% total fat (with 70% of total oil as DHA) that will deliver around 60 mg of DHA for each 0.5 mL of emulsion. 2. Placebo (soy oil) emulsion with no DHA. Dosing regime: Infants will be given 0.5 mL/kg/d in three divided doses three times daily (0.17 mL/kg/dose). Route: Enteral

Sample Size:
1244 infants.

Population:
Infants born at less than 29 weeks gestation.

Contact details:
For further details:
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Dr.SrinSrinivas Bolisetty, MD, FRACP
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B. Recruitment Ongoing in 2014:

1. Targeted Oxygenation in the Development of Premature Infants and Their Developmental Outcome – the TO₂RPIDO Study (NHMRC funded)

Aim:
To determine the outcomes of premature infants below 32 weeks gestation who are resuscitated with either 100% oxygen (100% O₂) or 21% oxygen (room air, RA) that is titrated to achieve specific pre-ductal SpO₂ levels.

Hypothesis:
Compared to 100% O₂, using RA to start the resuscitation of infants below 32 weeks gestation while maintaining target SpO₂ will:
- Primary outcome: Increase survival without major disability at 18-24 months of age.
- Secondary outcomes: Increase survival without major morbidities (e.g. bronchopulmonary dysplasia (BPD), retinopathy of prematurity (ROP), intraventricular hemorrhage (IVH, grade 3 or higher), cerebral palsy (CP), necrotizing enterocolitis (NEC)) and decrease oxidative stress.

Study Design: The TO₂rpido study is an international multi-centre randomised controlled clinical trial comparing 100% O₂ to 21% O₂ to initiate the resuscitation of premature infants below 32 weeks of gestation.

Eligibility: Mothers are eligible if they present to hospital with a risk of preterm delivery before 32 weeks gestation. This will be determined from the date of the mother’s last menstrual period (LMP) or from an early (i.e. first trimester) dating ultrasound if LMP is uncertain. In cases where neither is available, an infant with an estimated birth weight <1250g (50th percentile weight of infant at 31 weeks gestation) as determined by a pre-delivery ultrasound, may be included in the study. These are Australian parameters but may also be applied to other races where differences in growth parameters usually become significant only as the fetus approaches term.

Exclusion Criteria: Congenital abnormalities that impair oxygenation and neurodevelopment or are likely to be fatal e.g. cardiopulmonary abnormalities with arterio-venous admixing; aneuploidy e.g. Trisomy 21 (certain intellectual disability) or Trisomy 18 (fatal in early childhood). These may not be known prior to birth and the infant will excluded from the study if postnatal diagnosis is confirmed and a replacement randomization code will be generated.

Patient Recruitment and Consent: The principal investigator (PI) from each site will be an attending neonatologist. He/she and his team will be notified as per well defined clinical guidelines, of every mother who presents at risk of preterm delivery at that hospital and as standard of care, will counsel her regarding perinatal management. During counseling, information about the study will be provided for the parents and informed consent will be obtained if the parent is not in duress/sedated and has sufficient time (>6 hours from presentation to delivery, as per stipulation of local ethics committees) to understand the study. Paternal consent is not a stipulated necessity by the ethics committees as fathers are not always present at the mother’s presentation to hospital. Patient information and consent forms are available and approved by relevant ethics committees in English, Malay, Chinese, Arabic and Thai. Other translations will be developed as necessary when more countries join the study. Any infant who is withdrawn from the study after consent is obtained will be resuscitated according to local standard practices and a new randomisation code will be generated if needed.

Randomisation: Randomisation and patient data entry are conducted through a website
that can be accessed by standard computers and mobile devices. The website allows the coordinating centre to verify remote information and update study numbers. Information for consented patients is entered pre-emptively and randomisation codes are disclosed at birth. These are grouped into blocks of 10 and stratified by gestational ages (<27\textsuperscript{6} weeks and 28-31\textsuperscript{6} weeks) to ensure comparable treatment numbers. Multiple birth infants may account for up to 20\% of our study population and infants will be randomised individually to avoid cluster effects due to confounding influences from biological and genetic similarities or differences\textsuperscript{55} and which will be accounted by our statistical approach during analysis. Consent for the singleton and therefore, the independent twin, in an RCT assumes equipoise and causes no realistic problems when randomizing between infants in a twin pair. Hard copy data will be reviewed on a regular basis by the coordinating centre to verify remote randomization and data entry.

**Recruitment Start Date:**
2006

**Recruitment End Date:**
2015

**Contact Details:**
Julee Oei
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**C. Recruitment Starts in 2014:**

1. **The Capacity for Informed Consent during Labour**

   **Short title:** “Capacity for informed consent during labour”.

   **Primary Objective:**
   - To determine the capacity of pregnant women to comprehend and retain information (pregnancy and non-pregnancy related) during labour.

   **Secondary Objectives:**
   - To compare the efficacy of information provision at both 36 weeks gestation and in labour versus in labour only.
   - To compare efficacy of verbal versus written provision of information.
   - To assess immediate comprehension and retention of information.
   - To assess comprehension and retention of information through either approach 24-30 hours postpartum.

   **Study Design:**
   Prospective pilot study with the aim of starting a full study with the same protocol and apply for NHMRC funding.

   **Study Population:**
The study population involves all pregnant women booked at the Royal Hospital for Women, Sydney, Randwick and who present for a routine antenatal visit at 35+0-36+6 weeks of gestation. Women will be asked to complete a baseline assessment (questionnaire) 35+0-36+6 at week’s gestation, and then randomized to two groups as follows:
   - Group 1: Information given to the women in labour only.
   - Group 2: Information given to the women at 36 weeks and in labour.
Number of Participants:
Approximately 100 including 50 in each major group

Principal Site:
Royal Hospital for Women, Sydney, Randwick

Duration:
02/04/2014-02/04/2015

Inclusion Criteria:
- Women at 35+0 – 36+6 weeks of gestation (nulliparous or multiparous)
- Normal antenatal progress
- Ability to retain information

Exclusion Criteria:
- Maternal emergency conditions.
- Life threatening fetal congenital anomalies detected on scan.
- The mother with active psychiatric condition for which she is consulting a psychiatrist.

Contact Details:
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Prof.Alec Welsh
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Dr.Amanda Henry
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Aim:
To describe overall use of herbal and dietary supplements and specifically iron supplements before and during pregnancy.

Study population and study design:
This cross-sectional survey will be conducted at two hospital sites: the Royal North Shore Hospital and the Royal Hospital for Women. Pregnant women attending these hospitals for medical care between October 2013 and March 2014 will be approached for participation. Eligibility criteria include being pregnant at the time of the survey and able to complete the questionnaire in English. Eligible women will be given written and verbal information about the study.

The survey is a brief and anonymous questionnaire that will take approximately 5-10 minutes to complete. The survey questions have been developed following a review of literature. Survey development includes pilot testing on fifteen women attending antenatal appointments and subsequent review and revision if required.

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For further details please contact:
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3. Parental Response to Fetal or Postnatal Diagnosis of Congenital Heart Disease and Subsequent Infant Development Outcomes. Or Congenital Heart disease and Early support for family and Infant psychological Health (CHERISH).

**Aims:**
1) To systematically identify the prevalence, course and correlates of psychological stress and coping responses in parents of an infant diagnosed with major CHD during pregnancy or soon after birth, compared with outcomes reported by parents of healthy infants.
2) To assess infant neurodevelopment, attachment behaviour, and biobehavioural regulation, with particular focus on potential differences according to prenatal stress exposure.
3) To use the findings as a basis for recommendations for the development of tailored, evidence based interventions to address the psychosocial needs of infants with CHD and their families.

**Research Design:**
This study will consist of three groups of families including mothers, fathers, and their infants. The three groups will comprise of: parents of an infant diagnosed with complex CHD during pregnancy (Fetal diagnosis group), parents of an infant diagnosed with complex CHD soon after birth (Postnatal diagnosis group), and parents of a healthy infant (Healthy control group). Complex CHD is defined, in this study, as congenital heart disease requiring surgical intervention in the first six months of life. The fetal diagnosis group and the healthy control group will be assessed at four time points in total, with the first assessment being at 24, 28 weeks gestation. All groups will be assessed at 6weeks, 8 months, and 12 months after birth.

**Sites of Recruitment:**
1. The Children's Hospital at Westmead
2. Sydney Children's Hospital (Randwick)
3. Royal Hospital for Women
4. Westmead Hospital
Department of Women's Health (Obstetrics and Midwifery)

**Time Frame:**
April 2014 - Feb 2017

**Contact Details:**
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4. When Does the Neonate Start Forming Rouleaux? (Neonatal Rouleaux Study)

**Aim:**
To qualitatively assess rouleaux formation by blood film examination at the time of birth and during the first two weeks of life.

**Hypotheses:**
- There is rouleaux formation in the neonate at the time of birth.
- Rouleaux formation increases during the first two weeks of life.

**Participants:**
To address the stated aims, this study will involve two population groups. One group will be term neonates and the other group will be preterm neonates. The term neonates have been selected to compare rouleaux formation at the time of birth and at approximately 48 hours to assess changes in rouleaugenicity in the immediate newborn period. The preterm neonates have been selected to compare rouleaux formation serially over the first two weeks of life. The study has been designed so that all blood samples are collected at times when the baby is already having blood collected as part of their routine care.

The blood films of 24 term and 24 moderate preterm neonates will be examined for the presence of rouleaux. A spot of blood is required for each examination, which will be smeared on a slide and sent to SEALS (South Eastern Area Laboratory Services) for fixation and storage. The blood films will be collected by a single investigator (Dr Timothy Schindler). Each blood film will be assigned a rating based on the amount of rouleaux formation from 0 to 4+ (where 0 represents no rouleaux formation, 1+ represents minimal rouleaux formation and 4+ represents significant rouleaux formation) by two investigators. The investigators (Dr Timothy Schindler, Dr Timothy Brighton) will assess each film independently. A senior staff haematologist (Dr Timothy Brighton) will assist in the interpretation of blood films and provide significant guidance in the establishment of this rating scale.

**Sites:**
Newborn Care Centre, RHW & SEALS laboratory, POWH.

**Contact Details:**
For further details please contact:
Dr Timothy Schindler
Tim.Schindler@sesiahs.health.nsw.gov.au

5. A Family Integrated Care Model for NICU.

**Short Title:**
FiCare

This study will evaluate the efficacy of the Family Integrated Care model in a multicenter cluster randomized controlled trial of 16 NICUs across Canada and Australia.

For further details please contact:
A/P Kei Lui
Kei.lui@sesiahs.health.nsw.gov.au
D. Honours Projects:

1. Recruitment Starts in 2014:

1. Correlation and Synergy between the Delta Myocardial Performance Index (MPI) and Aortic Isthmus Index as Markers of Unilateral Fetal Cardiac Strain. (Aortic Isthmus Study)

Aims/hypothesis:
Both the Aortic Isthmus Index and the Delta Myocardial Performance Index have been proposed as useful markers for unilateral fetal cardiac function or strain. Individually these are both novel research imaging tools. We hypothesise that these separate measures of unilateral ventricular performance and respective peripheral impedances will correlate. Furthermore we hypothesise that alterations in these measures will be additive and will aid in differentiation of pathological cases of unilateral cardiac strain.

Place of recruitment at the RHW:
Antenatal clinic, delivery suite, post natal ward, ultrasound department

Methodology:
This study should look at a number of interlinked facets within this area:

1. Evaluation of repeatability of the AoI within our population. This has been previously evaluated by other groups but the tool is novel to us (though simple in application and similar to our other research tools). A small number of cases will be sufficient for this (n=10)

2. Evaluation of the correlation between AoI and delta MPI in a cross-sectional population. We anticipate a strong correlation (≥0.8) though will power this part of the research to detect a lower correlation. At an alpha of 0.05 and a power of 0.95 we would anticipate a sample size of just 8 to show a correlation coefficient of 0.9 and of 25 to show a correlation coefficient of just 0.6. This is the minimum level we would consider acceptable so in order to have some latitude we anticipate a sample size of 30 for this component. This would also detect a correlation coefficient of 0.5 if the alpha level was 0.05 and the power 0.8 as commonly used in research (n=23 necessary).

3. The Honours student will be involved in acquiring and analysing data that will show not only the correlation between these but how that correlation alters with gestation. However we anticipate this to represent a larger study that will be ongoing and typically would require numbers in excess of 300. Its completion may not be feasible within the Honours time period but the student will be a valued author on any publication.

4. An evaluation of a limited number of pilot pathological cases to determine whether the Aortic isthmic index, delta MPI or a combination of the two, are likely to be more predictive of deviation from the normal range and therefore need for intervention. This is also likely to be an ongoing study so this data will only be pilot in nature.

Time frame:
01/03/014-01/11/014
2. Application of Automation to the Fetal Myocardial Performance Index (MPI) to Determine Repeatability of a Digital System Compared with Human Measurement

Hypothesis:
Hypothesis of this study is that an automated technique for measurement of the fetal MPI will be more repeatable than currently used subjective methodology.

Inclusion/Exclusion criteria:
Inclusion criteria – Patients with normal pregnancies
Exclusion criteria – Patients with complicated pregnancies

Place of recruitment at the RHW:
Mainly in the antenatal clinic; patients may be recruited at the morphology scan.

Methodology:
The fetal myocardial performance index (MPI) is a value measured through fetal pulsed-wave Doppler ultrasound. MPIs outside of the normal range may indicate cardiac dysfunction. Currently, sonographers obtain the MPI from ultrasound images manually by measuring particular cardiac time intervals using a cursor. This manual determination of time intervals creates the potential for imprecision in measurements and significant inter- and intra-observer measurement variability.

This study intends to undertake a multi-centre international (UK, USA, Australia, Spain and Saudi Arabia) evaluation using online technology to compare automation with human evaluation for determination of the fetal MPI.

The study investigators wish to evaluate the automation process prospectively, using individual waveforms from the left ventricle of a small number of cases (n=25). Each individual waveform will be used in triplicate and placed into an arbitrary order (ie. n=75). Observers at the other centres involved in the study will manually calculate the MPI for the 75 waveforms through online means. The same waveforms will be analysed using the automated process, and the data yielded from both methodologies will be compared.

An additional sub-study will likely include the comparison of automation with human evaluation for the determination of the fetal MPI for the right ventricle.

Additionally, we wish to evaluate the beat-to-beat variability of MPI for the left ventricle only. The reason for choosing left only is that it is measured directly from a single waveform, whereas the right is generally (after about 26 weeks gestation) measured from two separate waveforms. Our evaluation of beat-to-beat variability will comprise 10 separate waveforms (2 sets of 5 successive) from each of 30 fetuses. At present precise power calculations are impossible as this is pilot data. Should we find a notable variation
in range with gestation then we will need to design a broader study evaluating the relationship between beat-to-beat variability and gestation. However at present we do not have this information.

**Time frame:**
01/03/014-01/11/014

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**E. Independent Learning Projects (ILP):**

**1. RecruitmentFinished in 2013:**

**1. Outcomes of Stage 1 Twin-Twin Transfusion Syndrome (TTTS) Referred to the NSW Fetal therapy Centre: the NSW Perspective**

**Aims:**
This study aims:
- To evaluate the outcome for cases referred to the NSW Fetal Therapy Centre as Stage 1 TTTS.
- To gain an understanding of current therapeutic strategies for TTTS including the potential for providing laser therapy for stage 1 TTTS.
- To compare progression and regression of TTTS in our local population with the international literature.

**Study Population:**
Patients who are referred to the NSW Fetal Therapy Centre with a diagnosis of Stage 1 TTTS-50

**Start Date:**
18/03/2013

**End Date:**
02/12/2013

**Contact Details:**
Ms Elen Hinch
ILP Student, UNSW
z3375990@student.unsw.edu.au
2. Twin Laser Outcome Study
An Audit of Immediate Outcomes for Monochorionic Diamniotic Twins Following Laser Therapy for Twin-Twin Transfusion Syndrome.

**Aims:**
This project aims to update the previous audit of the outcomes of the monochorionic twins undergoing laser therapy at the RHW. Laser therapy for twin-twin transfusion syndrome has been performed at the RHW since June 2003. A previous audit of the cases between June 2003 to June 2008 was published in 2010. We wish to update this update which focuses upon immediate survival of twins in the neonatal period.

**Study Population:**
This is an audit that will retrospectively be looking at the procedures performed and outcomes. There will be no need to contact patients directly. Patients who have undergone laser therapy for twin-twin transfusion syndrome (medical records only) – 50.

**Start Date:**
18/03/2013

**End Date:**
02/12/2013

**Contact Details:**
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3. Recruitment Starts in 2014:

1. Breastfeeding and the Developmental Outcomes of Very Premature Infants-ILP Project
The aim of this study is to compare the neurodevelopmental outcomes at corrected age 2-3 years between breast fed and formula fed infants at discharge born at GA <29 completed weeks using a population based retrospective cohort study of infants treated in 10 NICUs in NSW & the ACT between January 1 2001 and December 31 2009.

Methodology:
This is a population-based longitudinal cohort study of very premature babies (<29 weeks gestation) admitted to any of the 10 Neonatal Intensive Care Units (NICUs) in New South Wales (NSW) and the Australian Capital Territory (ACT) in Australia during the 7-year period from 1st January 2001 through 31st December 2009. Infants with major congenital anomalies were excluded from this study. A full description of the NSW and ACT neonatal service organization and networking, medical and nursing staffing and roster structures of the collaborating NICUs is available elsewhere.

Data source:
I. Neonatal Intensive Care Units’ (NICUS) Data Collection is an ongoing prospective state-wide audit of infants admitted to the 10 NICUs in NSW and the ACT during the neonatal period for one of the following reasons: (1) gestation age <32 weeks, (2) birth weight ≤1500 grams, (3) assisted ventilation (mechanical ventilation or continuous positive airways pressure, high flow gas >1L/min) for four hours or more commenced during the first 28 days of life, or (4) major surgery (opening of a body cavity first performed in the first 28 days of life), or therapeutic hypothermia, or insertion of a central line for four hours or more commenced during the first 28 days of life. Definitions and accuracy of the database have been documented elsewhere.

II. Neonatal Intensive Care Units’ Follow-up Data Collection is an ongoing prospective state-wide audit at 2-3 years of age, corrected for prematurity, of infants born less than 29 weeks’ gestation and admitted to a NSW or ACT NICU.

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2. TAPS and TRAPS
Uncommon complications of monochromic twin pregnancies: Twin Anemia Polycythemia Syndrome (TAPS) and Twin Reversed Arterial Perfusion (TRAP)
The aim of this study is to conduct an audit of pregnancy management and immediate outcomes of monochromic diamniotic twin pregnancies affected by TAP or TRAP sequence.

Patients referred to the NSW Fetal therapy Centre at the Royal Hospital for Women for management of either condition from April 2007 – 2014 will be included and the relevant data will be entered into the study database. Patients who have been delivered at the RHW will have all information collected from the RHW internal database. There is no direct patient contact.
Patients who return to their referring hospital for birth will be identified at the start of
the audit, then appropriate ethical permission sought from the relevant hospitals via
SESLHD HREC for access to birth outcome and neonatal data. This will be achieved via
Access Request Forms. There is no direct patient contact.

**Methodology:**
Researchers will develop a study database, identify the subjects for audit and commence
data entry relevant to the subjects. It is anticipated that 20 subjects of TAPS are
anticipated antenatally, and 15 TRAP cases, will be the sample size to be compared to
our existing databases of 140 TTTS patients and 100 uncomplicated MCDA Twins.

**Start Date:**
01/03/2014

**End Date:**
01/04/2015

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3. **The role of Myocardial Performance Index in complicated monochorionic twin pregnancies**

**Aims/hypothesis:**

**Aims:**
- To compare ventricular function in complicated monochorionic, diamniotic (MCDA)
twin pregnancies versus uncomplicated MCDA pregnancies, through use of the
ultrasound-derived Myocardial Performance Index (MPI)
- To assess whether any differences that exist are potentially sufficient to be useful
in clinical practice to determine need for treatment and/or delivery of complicated
MCDA pregnancies

**Hypothesis:**
- MPI and/or AoI will, in conjunction with routinely assessed ultrasound Doppler
measurements, predict which monochorionic diamniotic pregnancies with early
complications (e.g. early stage TTTS) will progress to a stage requiring
intervention.

**Inclusion/Exclusion criteria:**

**Inclusion criteria:**
- All participants must have had normal cardiac morphology at morphology scan.
  For control group, normal morphology scan (including normal placental position)
  required for inclusion.
- Willingness to participate in the study and understanding that means having 1-4
  additional ultrasound scans during the pregnancy (for control
  group/uncomplicated pregnancy cohort) and, for complicated pregnancy groups,
  having research ultrasound measurements taken at least once at the time of the
  clinically indicated ultrasound for surveillance of their pregnancy condition.
- Having read the patient information and signed the consent for the study.
Four separate groups will be evaluated:

- Uncomplicated singleton pregnancy (Background Control group). Defined as having no maternal or fetal complications during the pregnancy.
- Maternal cholestasis of pregnancy. Defined as the combination of clinical symptoms (itch) and elevated fasting bile acids (>95th centile). For analysis this group will be subdivided into those with bile acids >4X normal reference range (>30), as previous research suggests this group is at higher risk of adverse perinatal outcome (Glantz, 2004), and those with bile acids which are elevated but <30.
- Monochorionic Twins with or without complications (MCDA group). Defined as pregnancies with twins that have been identified in the first trimester of pregnancy to share one placenta but have two separate amniotic fluid sacs.
- Pregnant women with intrauterine growth retardation (IUGR group). Defined as having fetuses at or below the 5th percentile for gestational age, +/- reduction in amniotic fluid +/- other Doppler blood flow abnormalities.

Exclusion criteria:

- Women with an abnormal morphology scan.
- Mothers who are on medications with the potential to significantly affect fetal heart function.
- Refusal to participate in the research.
- Psychiatric illness precluding informed patient consent.

Time Frame:
01/03/2014-01/12/2014

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4. Diabetes Mellitus in Mothers with Twin Pregnancy

Aims:
1. To determine number of women (proportion) with twins with GDM or pre-GDM
2. To determine change in GDM incidence over time in women with twins
3. To determine predictors of GDM in women with twins: including age, BMI, Family history, ethnicity, assisted reproductive history and to determine whether women would have been detected according to new 2013 ADIPS GDM criteria
4. To determine gestational age of detection of GDM, and what screening/ testing was done in women with twins
5. To determine what treatment women with GDM received
6. To determine the maternal outcomes of women with DM vs. no DM
7. To determine neonatal outcomes of infants of mothers with GDM vs. no GDM
**Study Details:**
This is a retrospective cohort study of women with a twin pregnancy who booked and delivered between January 2004 and December 2013, at Royal Hospital for Women (RHW), Randwick.
Women who delivered twins at RHW from 2007-2013 will be identified from the Obstetrix database. In addition, the hospital database that preceded the implementation of the Obstetrix database in 2007 will be searched for twin births who delivered 2004-2007. The Obstetrix and hospital database collect information on women who delivered >=20 weeks gestation. Women with pre-pregnancy diabetes mellitus (pre-GDM) and gestational diabetes mellitus (GDM) delivered at RHW will be identified from the diabetes clinic database, as DM may be under-reported in Obstetrix/ hospital database).

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